

BREAKOUT SESSION DISCUSSION POINTS – HEALTHCARE

NIOSH Personal Protective Equipment
Conformity Assessment Public Meeting

1) Who defines the BHSRs for your industry?

- *FDA has been included in our activities
- *OSHA
- *Joint Commission drives implementation
- *CDC guidelines and recommendations
- AHA – American Hospital Association
- SEIU – Service Employees International Union
- *Users - AMA, ACOEM, ANA, AOHP, ACGHI, AIHA, ASTHO
- Infection Prevention – APIC
- NRC – Ionization Energy
- AAMI

2) How should the BHSRs be established?

- General Duty Clause
- TB and Biological/Infection Control Guidelines – CDC---
OSHA/Joint Commission
- Everything else – laser use, chemotherapy, PPE
- Worker and Patient Protection Synergy needed
- Hazardous Waste Protocols also

3) Who should address what PPE is needed to meet BHSRs?

- Need selection and application guide aligned for patient and worker, community health and safety
- Education programs for HCW's in general
- EPA model for exposures and PPE needed
- Comes down to threat recognition and action by the worker, no system of checks and balances
 - Health and safety driven – initial training, unit specific training
 - System protection is emphasized, not worker protection

Need strong risk assessment and OSH professionals

4) Who determines the technical standards that demonstrate the BHSRs are met?

- Voluntary FDA and CDC (advisory committee APIC), NIOSH
 - Practice of medicine is not regulated by the agencies, the devices are regulated
- ACOEM (MC)

This was a challenging question for our group. Answers did not jump out! We noted the European Union Approach – the government provides the scheme for identifying basic health and safety requirements and the standards – facilitates the safety culture

5) How are conformity assessment requirements linked to PPE types?

- The need for CA was emphasized, beyond device approval, risk driven conformity – when can the cheap one be used, when is the more specific device needed, how are devices assessed?

Planned event and unplanned events

Missing periodic assessment – use patient control measures/assessments to indirectly assess occupational safety and health – mesh the two together

Procurement issues also considered!! Value Analysis Committee to assess patient concerns, worker concerns and procurement decisions.

Anything else we need to consider?

- Have the key partners at the table
- Failure is the lack of use, compliance issue, not CA of the certified product
 - CA should be considered by the industry
 - Respiratory regulation is working but procurement issues still exist